

States are more likely than non-Hispanic Whites to experience heat waves, powerful hurricanes, sea level rises, and floods. It is estimated that Hispanic and Latino people are 43 percent more likely to live in an area expected to be too hot to work a full day outside due to climate change. And communities are responding. Across the United States, thousands of people have joined together to help Puerto Rico—including in Illinois—where the Puerto Rican Agenda is working to provide immediate relief to those affected by natural disasters. I support their efforts and President Biden's approval of a major disaster declaration for Puerto Rico.

Tackling environmental injustice doesn't end there. Earlier this year, activists and community leaders in southeast Chicago raised concerns with the development of a metal shredder facility. The Chicago Health Department and the Environmental Protection Agency conducted a health impact assessment, finding the metal recycling plant would have increased air pollution and negatively impacted the mental health of residents. As a result, the city blocked the development. This story is not unique to Chicago; Latino communities across the United States have mobilized to make their voices heard and protect our communities.

We also saw this tenacity during the pandemic. Millions of Hispanic and Latino people served as frontline workers—treating patients, feeding communities, and working around the clock to disinfect schools, stores, and health centers at a grave personal cost. Today, Hispanic or Latino persons are twice as likely to be hospitalized for COVID-19 and 1.8 times more likely to die from the virus, due to health disparities and continuous exposure. We must never forget the contributions they made, which have supported our Nation during one of its most difficult moments.

Countless Latino leaders have overcome systemic injustices to succeed and inspire the next generation of leaders. As we celebrate Hispanic Heritage Month, we recognize the value the Latino community brings to our country through its work and culture. Resilience and love shine through in all that the community does and will continue to make us a stronger country for years to come.

NOTICE OF A TIE VOTE UNDER S. RES. 27

Mr. PETERS. Mr. President, I ask unanimous consent to print the following letter in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

U.S. SENATE,
COMMITTEE ON HOMELAND SECURITY AND
GOVERNMENTAL AFFAIRS,
Washington, DC, September 28, 2022.
To the Secretary of the Senate:

PN 2457, the nomination of Colleen Joy Shogan, to be Archivist of the United States,

vice David S. Ferriero, having been referred to the Committee on Homeland Security and Governmental Affairs, the Committee with a quorum present, has voted on the nomination as follows—

On the question of reporting the nomination favorably with the recommendation that the nomination be confirmed 7 ayes to 7 noes.

In accordance with section 3, paragraph (1) (A) of S. Res. 27 of the 117th Congress, I hereby give notice that the Committee on Homeland Security and Governmental Affairs has not reported the nomination because of a tie vote and ask that this notice be printed in the RECORD pursuant to the resolution.

GARY C. PETERS,
Chairman.

INFLATION REDUCTION ACT OF 2022

Ms. CORTEZ MASTO. Mr. President, I rise today to clarify a colloquy between myself and Chairman WYDEN placed in the CONGRESSIONAL RECORD on August 6, 2022. The statement in the RECORD references geothermal energy as applicable to the new "section 48D" of the Tax Code added by section 13702 of the Inflation Reduction Act. The statement should have referenced that section as "section 48E." As explained in that colloquy, geothermal will qualify for the production and investment tax credits included in sections 13701 and 13702 of the Inflation Reduction Act.

FOOD AND DRUG ADMINISTRATION USER FEE REAUTHORIZATION

Mrs. MURRAY. Mr. President, I ask unanimous consent to have printed in the RECORD a copy of the transmittal and commitment letters from the Secretary of Health and Human Services to the chair and ranking member of the Committee on Health, Education, Labor, and Pensions of the Senate and the chair and ranking member of the Committee on Energy and Commerce of the House of Representatives regarding reauthorization of the Prescription Drug User Fee Act, Medical Device User Fee Amendments, Generic Drug User Fee Amendments, and Biosimilar User Fee Act.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

THE SECRETARY OF HEALTH
AND HUMAN SERVICES,
Washington, DC, January 12, 2022.
Hon. PATTY MURRAY,
*Chair, Committee on Health, Education, Labor
and Pensions, U.S. Senate, Washington,
DC.*

DEAR CHAIR MURRAY: The Prescription Drug User Fee Act [PDUFA] as reauthorized by the Food and Drug Administration Reauthorization Act [FDARA P.L. 115-52], expires at the end of Fiscal Year 2022. With this letter the Administration is providing our recommendations for the reauthorization of PDUFA for the Fiscal Years 2023-2027 [PDUFA VII].

Under PDUFA, the revenues generated from fees paid by the pharmaceutical industry have been used to expedite the process for the review of new prescription drugs and to support and augment regulatory science

and drug development. The expenditure of these funds is in accordance with the statute and provides resources to meet the performance goals and procedures that were developed by the Food and Drug Administration [FDA] in consultation with representatives of regulated industry. FDA estimates that the fees negotiated in PDUFA VII will average approximately \$1.4 billion per year. PDUFA has proven to be an extremely effective program that has transformed the U.S. drug review to be the fastest in the world, while setting the global gold standard for quality, efficacy, and safety.

Throughout this process, the FDA has solicited input and worked with various stakeholders, including representatives from consumer and patient advocates, academic research, and health provider groups, and negotiated with the pharmaceutical and biotechnology industries, to develop reauthorization recommendations for PDUFA that would build upon and enhance the success of the program. In addition, we have complied with the statutory requirements to solicit public comments on our recommendations, and the summary of public comments is posted on the agency web site and enclosed with this letter.

Our recommendations build upon the successes of existing programs and performance goals with improvements and expansions to address areas of emerging regulatory science and drug development. For example, this includes, but is not limited to:

Investing critical resources in the Center for Biologics Evaluation and Research to support development, review, and approval of cell and gene therapy products;

Introducing new pilot programs to expedite patient access to novel uses for existing therapies, advance rare diseases development through efficacy endpoint development, and improve the quality and acceptability of real-world evidence;

Enhancing the drug safety system through optimizing the Sentinel Initiative capabilities and improving Risk Evaluation and Mitigation Strategy (REMS) assessments;

Introducing new enhancements related to product quality reviews, chemistry, manufacturing, and control approaches, and advancing the utilization of innovative manufacturing technologies;

Enhancing the use of digital health technologies to support drug development and review, along with leveraging modern technology to accelerate FDA's data and technology modernization;

Improving management of user fee resources through advancing FDA's Resource Capacity Planning function and continuing activities to enhance financial transparency.

The following five enclosures are provided for your consideration: The proposed PDUFA VII statutory language; a redline of current law; the Justifications of Proposed Statutory Changes for Reauthorization of PDUFA in Fiscal Years 2023 through 2027; the PDUFA Reauthorization Performance Goals and Procedures in Fiscal Years 2023 through 2027; and the summary of public comments.

Thank you for the opportunity to present our recommendations to reauthorize this vital program. We would be pleased to brief your staff on the details and want to work closely with Congress to reauthorize the program in a timely manner. The Office of Management and Budget has advised that the bill and the enclosed performance goals are in accord with the Administration's program.

Sincerely,

XAVIER BECERRA.